CLAIMS

1. A process for the production of sertraline hydrochloride Form-V comprising the steps of:

   a) dissolving or suspending sertraline mandelate in a protic solvent or a mixture of protic solvents;

   b) reducing the pH of the solution or the suspension by adding hydrochloric acid in water to form a clear solution; and

   c) isolating sertraline hydrochloride Form V.

2. The process as claimed in claim 1, wherein protic solvent(s) used in step (a) is selected from the group comprising of alcohol , water or mixtures thereof.

3. The process as claimed in claim 2, wherein said alcoholic solvent used in step (a) is selected from the group comprising of methanol, ethanol, n-propyl alcohol, isopropyl alcohol, n-butyl alcohol, t-butyl alcohol and isobutyl alcohol or a mixture thereof.

4. The process as claimed in claim 3, wherein said alcoholic solvent is isopropyl alcohol.

5. The process as claimed in claim 1, wherein said step(a) of dissolving or suspending is achieved by heating and / or stirring.

6. The process as claimed in claim 1, wherein said step (a) of dissolving or suspending sertraline mandelate in a solvent is carried out at temperature in the range of 20 to 90 °C.

7. The process as claimed in claim 6, wherein said range of temperature is 25 to 80°C.

8. The process as claimed in claim 7, wherein said range of temperature is 25 to 30°C.

9. The process as claimed in claim 1, wherein pH is reduced to the range of 1 to 3 in step (b).

10. The process as claimed in claim 9, wherein pH is reduced to the range of 1 to 2.

11. The process as claimed in claim 1, wherein isolation of sertraline hydrochloride Form V in step (c) is carried out by cooling the contents of step (b).

12. The process as claimed in claim 11, wherein the cooling is effected by allowing the solution to attain room temperature on its own or with mild coolants comprising of cold water, water, alcohol or mixtures thereof.

13. The process as claimed in claim 12, wherein said alcohol is selected from the group comprising of monohydroxy alcohols, dihydroxy alcohols or mixtures thereof.

14. A process for preparation of an immediate release pharmaceutical composition of sertraline hydrochloride Form - V, comprising mixing sertraline hydrochloride Form-V, of particle size below 20μ is not less than 90 % with pharmaceutically acceptable diluent, carrier or excepient.

15. The process for preparation of a pharmaceutical composition as claimed in claim 14, wherein the impurity level in sertraline hydrochloride Form V used is not more than 0.50% comprising of both known and unknown impurities.

16. The process for preparation of a pharmaceutical composition as claimed in claim 15, wherein the sulphated ash in sertraline hydrochloride Form V is not more than 0.2%.

17. The process for preparation of a pharmaceutical composition as claimed in claim 15, wherein the heavy metals in sertraline hydrochloride Form V used is not more than 20 ppm.

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18. The process for preparation of a pharmaceutical composition as claimed in claim 14, wherein the assay by titration of sertraline hydrochloride Form V is between 98.0 to 102.0 % on anhydrous basis.

19. The process for preparation of a pharmaceutical composition of as claimed in claim 14, wherein the residual solvents in the active ingredient sertraline hydrochloride Form V are :

| | | |
|---|---|---|
| (a) isopropyl alcohol | : | not more than 2000 ppm |
| (b) methanol | : | not more than 100 ppm |
| (c) acetone | : | not more than 100 ppm |
| (d) methylene chloride | : | not more than 200 ppm |

20. The process for preparation of a pharmaceutical composition as claimed in claim 14, wherein the microbial limits in active ingredient sertraline hydrochloride Form V are :

| | | |
|---|---|---|
| total aerobic count (cfu/g) | : | not more than 1000 |
| total fungal count (cfu/g) | : | not more than 100 |
| E.Coli | : | should be absent. |

21. A process for the preparation of sertraline hydrochloride Form - V, substantially as herein described, particularly with reference to the foregoing examples.